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SECTION 12

510(K) SUMMARY K010113

This 510(k) summary of safety and effectiveness for the Laser Mechanisms, Inc., Laser Scanning System is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	Laser Mechanisms, Inc.
Address:	P.O. Box 2064 Southfield, MI 48037
Manufacturer:	Laser Mechanisms, Inc.
Contact Person:	Mr. Jeffrey Hocking Director of Regulatory Affairs, QA & Security
Telephone:	248-474-9480 248-474-9277 (Fax)
Preparation Date: (of the Summary)	December 2000
Device Name:	Laser Scanning System
Common Name:	Scanner - an accessory to a medical laser for use in dermatology and plastic surgery
Classification Name:	None - the scanner has not be classified as a separate device - it is an accessory to a laser surgical instrument for use in plastic surgery and in dermatology (see: 21 CFR 878.4810). Product Code: GEX Panel: 79
Predicate devices:	Scanners marketed by Sahar Technology (SoftTouch Scanning Device), Clinicon (SureScan), and Jenoptik (JenaScan) were specifically cited. There are numerous scanners which have been cleared for use with lasers with dermatology indications.
Device description:	The Laser Mechanisms Scanning Device is microprocessor-controlled accessory for lasers in dermatology and plastic surgery. The scanner guides the laser energy over the skin in selected patterns during removal of soft tissue and hair under the conditions of labeling described in the laser operator manual.

Indications: As an accessory to lasers used in dermatology and plastic surgery the Laser Scanning System does not have its own indications but refers the user to the indications for use or intended uses in the manual accompanying the laser.

Specifically, the Operator's Guide states: Please refer to the User's Manual for the laser for additional information regarding indications and instructions for use, warnings or precautions, and other related information.

The System is a restricted device and is labeled: "CAUTION: Federal (US) law restricts the use of this device to licensed professionals."

Performance Data: None required.

CONCLUSION: Based on the information in the notification Laser Mechanisms believes that the Laser Scanning System is substantially equivalent to the cited legally marketed predicate under the conditions of labeling for the System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Jeffrey Hocking
Director of Regulatory Affairs,
Quality Assurance and Security
Laser Mechanisms, Inc.
P.O. Box 2064
Southfield, Michigan 48037

Re: K010113
Trade/Device Name: Laser Scanning System
Regulation Number: 878.4810
Regulatory Class: II
Product Code: GEX
Dated: January 15, 2001
Received: January 16, 2001

Dear Mr. Hocking:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 8

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K010113

Device Name: Laser Mechanisms Laser Scanning System

Indications for Use Statement:

The Laser Mechanisms Laser Scanning System is intended for use under conditions described in the manual accompanying the laser to which it is attached as an accessory. Laser Scanning System users are directed to refer to the laser manual for indications and instructions for use, warnings or precautions, and other related information.

Specifically, the Operator's Guide states: Please refer to the User's Manual for the laser for additional information regarding indications and instructions for use, warnings or precautions, and other related information.

CAUTION: Federal (US) law restricts this device to use by licensed professionals.

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010113

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The Counter Use ___
(Per 21 CFR 801.109)